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10/567,351

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Ralf Himmelreich

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EXAMINER

CRANE, LAWRENCE E

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,351	<b>Applicant(s)</b> HIMMELREICH ET AL.	
	<b>Examiner</b> Lawrence E. Crane	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on February 6, 2006 (Prelim. Amdt.).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/04/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

The Abstract of the Disclosure is objected to because it does not meet the requirement of the MPEP for US application. Correction is required. See MPEP §608.01(b).

Applicant is reminded of the proper content of an abstract of the disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplifications of a species could be illustrative of members of the class. For processes, the type of reaction, reagents and process conditions should be stated, and generally illustrated by a single example unless variations are necessary. Applicant is respectfully reminded that abstracts are limited to a maximum of 250 words by the MPEP.

Complete revision of the content of the abstract is required on a separate sheet. The Abstract presently of record is not in US format.

No claims have been cancelled, claims **11, 18 and 24-31** have been amended, the disclosure has been amended at page 1, and no new claims have been added as per the preliminary amendment filed February 6, 2006. One Information Disclosure Statement (1 IDS) filed October 4, 2007 has been received with all cited non-US patent references, annotated and made of record.

Claims **1-32** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

The disclosure is objected to because of the following informalities:

Inspection of the specific embodiments at pages 17-18 of the disclosure reveals a need for minor grammatical corrections: e.g. "," needs to be replaced by -- . -- in terms like "pH 5,5," a term which in English should read -- pH 5.5 --. See also page 18 at lines 22-23, wherein the term " but 5 ml 25% (w/v) dextran sulfate " should be amended to read -- but was 5 ml 25%

(w/v) of aqueous dextran sulfate -- (emphasis added), or the like, in order for the entire sentence to be clearly understood.

Examiner respectfully suggests that the remainder of the disclosure should be inspected for similar errors in English grammar, usage, and punctuation.

Appropriate correction is required.

35 U.S.C. §101 reads as follows:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”

Claims **25-28**(single occurrences) **and 30**(2 occurrences) are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See for example Ex parte Dunki, 153 USPQ 678 (Bd. App. ,1967) and Clinical Products, Ltd. v. Brenner, 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

In claims **25-28 and 30** the term “use” (all occurrences) is a derivative of the verb -- to use --, and in view of the above judicial guidance, examiner respectfully suggests that said term should be replaced with alternative terminology not derived from the noted verb.

Claims **1-32** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Factors to consider in this analysis:

a) Actual Reduction to Practice? The instant disclosure has only exemplified processes wherein the isolation of the “biopolymer” “DNA” has been demonstrated. The specific embodiments have not described how to isolate all species encompassed by the generic term “biopolymer[s]” (polysaccharides, polypeptides, glycopeptides, etc., etc.) as suggested by the term “biopolymer” in instant independent claim **1**.

b) Disclosure of Drawings or Structural Chemical Formulas? This factor is not relevant to this particular analysis.

c) Sufficient relevant identifying characteristics? This factor is not relevant to this particular analysis.

d) Method of making the claimed invention? This factor is dealt with in the first paragraph of this analysis.

e) Level of skill in the art? This factor is not relevant to this particular analysis.

f) Predictability in the art? The instant art is highly predictable as revealed by the numerous relevant prior art citations kindly provide by applicant.

For the above stated reasons the instant claims have been found to lack adequate support from the written description.

Claims **1-32** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for process for the separation of DNA from various plant sources wherein polyethylene glycol 8000 or an oligosaccharide-in-solution equivalent is present as a substitute, does not reasonably provide enablement for the multitude of different processes necessary to effect the efficient separation of any type of “biopolymer” from any specific source material in the absence of the process assistance of polyethylene glycol 8000 or an equivalent to avoid the “massively disturbed” result admitted by applicant twice at pages 17-18 of the disclosure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of “undue experimentation” is appropriate are as follows:

In view of the analysis of the previous rejection wherein many of the *Wands* factors have already been addressed, this rejection will be limited to a final conclusion concerning the need for undue experimentation.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure has been found to be excessive because, while the process is most broadly claimed to be effective in the separation/isolation of any “biopolymer” from any source, only DNA isolation from a few plant sources has been enabled by the instant specific embodiments. In addition, the contents of the remainder of the disclosure directed to the instant claimed subject matter appears to be entirely prospective, lending support to the conclusion that the instant disclosure has only enabled a very small fraction of the possible embodiments encompassed by the generic term “biopolymer.” Examiner respectfully suggests substantial narrowing of the scope of claimed subject matter.

Claim **21** is objected to because of the following informalities:

In claim **21** the term “4,8%” includes a punctuation error and should be amended to read -- 4.8 % --.

Appropriate correction is required.

Claims **1-32** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **1** the terms “biopolymer”, “magnetic particles,” and “additive” are generic to vast arrays of substances, only a few of which actually have been demonstrated to be effective participants in the instant claimed process, an issue addressed above. The issue here is lack of well defined metes and bounds, a problem which each of the noted terms suffers from at present. See also claims **18-21** wherein the term “additive” also appears without a complete definition thereof. Applicant is reminded that reliance on a disclosure definition will require application to 112, 2nd paragraph, standards to said definition, so amendment to conform to this standard is respectfully suggested as an accompaniment to arguments of the kind anticipated. See also claim **29** wherein the term “magnetic particles” is also incompletely defined.

In claim **1** at line 6, the term “to form a complex” implies an incompletely described process step for two reasons, first, the process being described involves adsorption of DNA to a silica surface, not complex formation, and the term “complex,” being term of art well known in

inorganic chemistry, is not appropriate in the present context because no ligand is binding to a metal ion. Examiner respectfully suggests alternative language is necessary to accurately describe the claimed subject matter in re the noted term. See also claim **27** wherein a similarly incomplete reference is made by inaccurate reliance on the term “complex.”

In claim **1** at lines 9-10, the term “washing ... under conditions in which said biopolymer is eluted” is technically confusing and/or misleading because a “washing” step is distinct from an “eluting” step. The former (washing) step typically relies on a high salt content buffer in order to avoid DNA elution, while the latter step typically relies on a low ionic strength buffer, or simply water, to effect elution of the adsorbed DNA. Clarification of the intended meanings is respectfully requested with the above distinctions in mind. See also claim **23** wherein the term “washing” has also failed to to be further defined by the failure to specify the conditions of said washing.

In claim **1** at lines 11-12, an incomplete reference is made to a critical limitation of the instant process, in particular the effect of an oligosaccharide/polysaccharide-containing-aqueous solution or an aqueous polyethylene glycol additive in permitting the execution of the process without errors caused by magnetic adsorbent particle clustering (see examples at pages 17-18). Examiner respectfully suggests that reference to -- polyalkylene glycol solutions -- or their -- oligosaccharide/polysaccharide equivalents in solution -- or the like that are not new matter needs to be present in the claim to completely describe the above noted critical limitation, a limitation which appears to have distinguished the instant claimed subject matter from the prior art. In the absence of such an amendment to the above noted limitation, said limitation has been found to have no patentable weight: see the prior art based rejections below, rejections which an appropriate version of the suggested amendment may render moot. See also claim **26** wherein a similarly incomplete reference is made to the critical limitation.

In claim **7** the term “selected from the group of” is technically erroneous. Applicant is respectfully reminded that a Markush preamble reads as follows: -- selected from the group consisting of -- (emphasis added). In addition at line 2, the term “guanidine thiocyanate, guanidine hydrochloride” is similarly erroneous and should be amended to read -- guanidine thiocyanate, and guanidine hydrochloride -- (emphasis added) in order to conform to the standard Markush group format. See also claims **8, 10, 12 and 30** wherein one or both of the same error(s) appear to have reoccurred.

In claim **24** the term “is an automated process” is generic to an unlimited array of possibilities, but said term has not been limited to any subset thereof by an adequately defined set of metes and bounds, and therefore renders the noted claim indefinite.

In claim **31** the term “silica magnetic particles” is subject matter not found in the claim depended from, thereby rendering the claim lacking in antecedent basis. Examiner respectfully suggests introduction of the term of art -- further comprising -- into the noted claim as one way to effectively address this rejection. See also claim **32** wherein a similar problem is present and would be similarly solved.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

“A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.”

Claims **1-32** are rejected under 35 U.S.C. §103(a) as being unpatentable over **Hawkins ‘628** (PTO-1449 ref. **AA1**) in view of **Smith et al. ‘945** (PTO-892 ref. **A**).

The instant claims are directed to a process for the isolation of a “biopolymer” (specifically enabled for DNA isolation) wherein silica-coated magnetic particles, a salt plus a polyalkylene glycol “additive” are present during the extraction and adsorption of DNA onto the silica surface of DNA and subsequently conventional steps are applied to wash away impurities and elute the DNA from the adsorbent. The option of automation of the process is also claimed.

Applicant is referred to the abstract of **Hawkins ‘628** wherein nearly all of the elements of the instant claimed isolation process as applied to obtaining DNA have been disclosed including the presence of variably optimizable concentrations of a salt and of a polyethylene glycol in the extraction/adsorption steps. In addition at column 2, lines 10-12, the potential for automation of the claimed process is also specifically disclosed.

**Hawkins ‘628** does not expressly disclose a silica coated magnetic particle as the adsorbent to which the DNA is adsorbed.



**Smith et al. '945** discloses a silica-coated magnetic particle as the adsorbent to which the DNA is adsorbed as part of a DNA purification protocol similar to that of **Hawkins '628**.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the silica-coated magnetic particles of **Smith et al. '945** for the carboxyl-coated magnetic particles of **Hawkins '628** in the course of routine experimentation to optimize the process disclosed by **Hawkins '628**.

One having ordinary skill in the art would have been motivated to combine these references because both the primary and secondary references are directed to similar protocols for the isolation of DNA from cellular sources, and which the disclosed methods share several common process elements.

Therefore, the instant claimed process for the isolation and purification of DNA from a cellular source by a process that relies on silica-coated magnetic particles and may be optimized by variations in the concentrations of salt and a polyalkylene glycol would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-**

**0651.** The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < <http://pair-direct.uspto.gov> >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec  
**02/22/2011**

/Lawrence E. Crane/

Primary Examiner, Art Unit 1623

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